



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-2002]

Thomas J. Whalen: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Thomas J. Whalen for a period of 10 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Whalen was convicted of multiple offenses; two of these are relevant to this debarment: one count of importation contrary of law-aiding and abetting and one count of healthcare fraud-aiding and abetting. The factual basis supporting Mr. Whalen's conviction is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Whalen was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of January 13, 2021 (30 days after receipt of the notice), Mr. Whalen had not responded. Mr. Whalen's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM-4029), Office of Strategic Planning and Operational Policy, Office of Regulatory

Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-8743, or at debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance. On September 15, 2020, Mr. Whalen was convicted, as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for the Eastern District of Pennsylvania, when the court entered judgment against him for multiple offenses, two of which are relevant to this debarment: one count of importation contrary to law-aiding and abetting in violation of 18 U.S.C. 545 and 2, and one count of healthcare fraud-aiding and abetting in violation of 18 U.S.C. 1347 and 2.

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein. The factual basis for this conviction is as follows: As contained in the information in Mr. Whalen's case, filed on October 25, 2019, to which he pleaded guilty, he was a doctor of osteopathy in the Commonwealth of Pennsylvania and the State of Delaware. From about January 2014 to about March 2018, Mr. Whalen engaged in a scheme to defraud Medicare, the U.S. Office of Personnel Management (OPM), and the Independence Blue Cross insurance company (IBC). Specifically, he purchased, imported into the United States, and distributed misbranded and non-FDA-approved injectable versions of REMICADE (infliximab), SYNVISIC/SYNVISIC ONE (hyaluronan), ORENCIA (abatacept), PROLIA/XGEVA (denosumab), and BONIVA (ibandronate sodium). He then injected his patients with these non-FDA-approved versions of these medications. Mr. Whalen billed Medicare, OPM, and IBC for the provision of the FDA-approved versions of these products.

As a result of this conviction, FDA sent Mr. Whalen, by United Parcel Service, on December 11, 2020, a notice proposing to debar him for a 10-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Mr. Whalen's felony conviction for two felony counts under Federal law related to this debarment, specifically for one count of importation contrary to law-aiding and abetting and one count of healthcare fraud-aiding and abetting, was for conduct relating to the importation into the United States of any drug or controlled substance, because he illegally imported unapproved and misbranded drugs into the United States and then distributed those misbranded and unapproved drugs to consumers in the United States.

In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Whalen's offenses and concluded that each felony offense warranted the imposition of a 5-year period of debarment, for a total debarment period of 10 years. The proposal informed Mr. Whalen of the proposed debarment and offered him an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Whalen received the proposal and notice of opportunity for a hearing on December 14, 2020. Mr. Whalen failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Whalen has been convicted of felonies under Federal law for conduct relating to the importation into the United States of any drug or controlled substance.

FDA finds that the offenses should be accorded a debarment period of 10 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Whalen is debarred for a period of 10 years from importing or offering for import any drug into the United States, effective (see DATES).

Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug or controlled substance by, with the assistance of, or at the direction of Mr. Whalen is a prohibited act.

Any application by Mr. Whalen for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2020-N-2002 and sent to the Dockets Management Staff (see ADDRESSES). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at <https://www.regulations.gov> or at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: March 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.